

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: SHAWN P. FOLEY LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK LLP 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090
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Date of mailing (day/month/year)	30 DEC 2004
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Applicant's or agent's file reference POLYPR-028	FOR FURTHER ACTION See paragraph 2 below
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International application No. PCT/US04/14325	International filing date (day/month/year) 07 May 2004 (07.05.2004)	Priority date (day/month/year) 09 May 2003 (09.05.2003)
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International Patent Classification (IPC) or both national classification and IPC IPC(7): C12Q 1/68; C12P 19/34 and US Cl.: 435/6, 91.1, 91.2
Applicant GENISPHERE INC.

1. This opinion contains indications relating to the following items:

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|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Kenneth R Horlick Telephone No. 703-308-0196 <div style="text-align: right; padding-top: 10px;"> DEBORAH A. THOMAS PARALEGAL SPECIALIST GROUP 1300 <i>dat</i> </div>
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/14325

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 1-34 and 36-39 YES

Claims 35 NO

Inventive step (IS)

Claims 1-34 and 36-39 YES

Claims 35 NO

Industrial applicability (IA)

Claims 1-39 YES

Claims NONE NO

2. Citations and explanations:

Claim 35 lacks novelty under PCT Article 33(2) as being anticipated by Berninger et al. This claim is drawn to a kit comprising a double-stranded RNA polymerase promoter having a sense strand and antisense strand, wherein the sense strand of said promoter comprises a single-stranded 3' overhang sequence. It is noted that "instructional materials" are not given patentable weight, as they relate to an "intended use" for the kit rather than to a kit component. Berninger et al. disclose such a kit in column 6, lines 30-42; also see Fig. 1.

Claims 1-34 and 36-39 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method wherein an oligodeoxynucleotide tail is attached to the 3' end of a single-stranded cDNA molecule, followed by annealing and ligation of a double-stranded RNA polymerase promoter such as is taught by Berninger et al., followed by initiation of RNA transcription to produce RNA molecules. Also, there is no teaching or suggestion of modifying the kit of Berninger et al. to include at least one enzyme for attaching an oligodeoxynucleotide tail onto the 3' end of a single-stranded cDNA molecule.

Claims 1-39 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.